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EXAMINER
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1648

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### **DETAILED ACTION**

Because the current set of claims was not properly amended, the reply/amendment filed on September 21, 2009 will not be entered or considered (see the reasons set forth below).

In addition, applicant's request for a new examiner has been denied because the Office does not allow applicants to change the examiner merely because the examiner is rejecting his/her claims. Applicant is not allowed to "shop around" for an examiner who may be more favorable.

### ***Drawings***

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the current drawings filed April 28, 2006 are not properly labeled (e.g., Figure 1, Figure 2, etc.). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. **The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will NOT be held in abeyance.**

### ***Specification***

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a

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nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

In addition, the spacing of the lines of the specification is such as to make reading difficult. New application papers with lines 1½ or double spaced on good quality paper are required.

### ***Status of Claims***

The numbering of claims submitted on September 21, 2009 is not accordance with 37 CFR 1.126, which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Applicant is advised to start with the previous version of the claims (filed on April 28, 2006; claims 1-30 pending with claims 1-10 canceled) and amend the claims, as indicated by § 1.121(c) of the M.P.E.P. (see below) to accurately describe the claimed invention such that it is fully distinguished from the cited references.

### ***Amendments to the Claims***

The claims submitted on September 21, 2009 have not been amended in accordance with U.S. Patent and Trademark practices.

According to § 1.121(c) of the M.P.E.P. (Manner of making amendments in applications), amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression:

(Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of “canceled” or “not entered” may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of “currently amended,” and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of

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any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of “currently amended,” or “withdrawn” if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as “withdrawn—currently amended.”

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of “original,” “withdrawn” or “previously presented” will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of “withdrawn” or “previously presented.” Any claim added by amendment must be indicated with the status of “new” and presented in clean version, i.e., without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of “canceled” or “not entered.”

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as “canceled” will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a “new” claim with a new claim number.

### ***Claim Objections and Rejections***

The claim objections and rejections below refer to the previous set of claims (filed on April 28, 2006; claims 1-30 pending with claims 1-10 canceled).

### ***Claim Objections***

Claims 18 and 27 remain objected to because of the following informalities:  
Claims 18 and 27 contain the phrase “a cleavage site for a protease..” after the period. Appropriate correction is required. Applicants are required to amend (change) the claims to address this objection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20 and 28 recite that “the GFP, fluorescent regions or the membrane penetration domains include the Gene - 3 Protein of the bacteriophage fd, gp 41 or Tat protein of the HIV – 1.” It is not clear how GFP, for example, can include phage or HIV-1 domains. Are these fusion proteins? Does each protein (GFP, fluorescent regions or the membrane penetration domains) contain Gene-3, gp 41 and Tat? One of ordinary skill in the art cannot determine the metes and bounds of the claims.

### ***Response to Arguments***

In the reply dated April 21, 2009, applicant argues that “a fusion protein can contain additionally either GFP or a membrane penetration domain.”

Applicants need to amend (change) the claims to state that “a fusion protein can contain additionally either GFP or a membrane penetration domain.” As written, the claim is confusing as stated above.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



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Claims 11, 12, 14, 18, 22, 24, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al. (Journal of Neuroscience, 2002, 22(12):4964-4972).

The claims are directed to fusion proteins comprising: regions selected from the group consisting of specific antigen binding regions, microtubule binding regions, and immune response triggering regions.

Yoshida et al. discloses fusion proteins comprising tau (microtubule binding region) and GFP.

Claims 11, 12, 14, 18, 22, 24, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Chapin et al. (Journal of Cell Science, 1991, 98:27-36).

The claims are directed to fusion proteins comprising: regions selected from the group consisting of specific antigen binding regions, microtubule binding regions, and immune response triggering regions.

Chapin et al. discloses fusion proteins comprising MAP4 (microtubule binding region) and  $\beta$ -gal.

Claims 11-13, 15, 22, 25, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Shi et al. (Biotechnology Letters, 2003, 25(10):815-819).

Shi et al. discloses a fusion protein consisting of erbB2 single chain antibody (scFv), Fc fragment of human IgG1 and IL-2.

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Claims 11, 14, 18, 22, 24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al. (Journal of Neuroscience Research, 2002, 67(5):625-633).

Zhou et al. discloses fusion proteins of human tau (microtubule binding region) with green fluorescent protein (GFP).

Claims 22, 23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobatake et al. (Journal of Biotechnology, 1995, 35:263-268).

The claims are directed to fusion proteins comprising: regions selected from the group consisting of antibody binding regions, and microtubule - binding regions, wherein the antibody binding regions include a component selected from the group consisting of Staphylococcal protein A (SPA), extracellular region of the Fc receptor CD 64, and regions thereof.

Kobatake et al. discloses fusion proteins comprising maltose binding protein and Staphylococcal protein A.

Claims 11, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehtio et al. (PNAS, 2003, 100(2):484-489).

The claims are directed to fusion proteins comprising: regions selected from the group consisting of specific antigen binding regions, microtubule binding regions, and immune response triggering regions and further comprising a cellulose binding region of the CipA protein.

Lehtio et al. discloses fusion proteins of the cellulose binding molecules (CBMs) such as CipA with a modified staphylococcal protein A (ZZ-domain).

### ***Response to Arguments***

In the reply dated April 21, 2009, applicant argues that the cited references do not teach the claimed invention and that the claimed invention is novel.

As stated previously, the claims, as written, are directed only to a fusion which can contain an antigen binding region or a microtubule region or an immune response triggering region. The fusion proteins of the cited references contain either an antigen binding region or a microtubule region or an immune response triggering region, and thus, meet the limitations of the claims as they are now written. There is no requirement in the claims that the fusion proteins inhibit cell division by binding to microtubules.

If applicant's fusion proteins contain all three (an antigen binding region, a microtubule region, and an immune response triggering region) then applicant should amend (change) the claims to state this.

For example, claims 11, 18 and 19 are directed to fusion proteins comprising: regions selected from the group consisting of specific antigen binding regions, microtubule binding regions, and immune response triggering regions and further comprising a cellulose binding region of the CipA protein.

As written, the claims are interpreted as being directed to a fusion protein containing an antigen binding region or a microtubule binding regions or an immune

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response triggering regions and further comprising a cellulose binding region of the CipA protein.

Lehtio et al. discloses fusion proteins of the cellulose binding molecules (CBMs) such as CipA with a modified staphylococcal protein A (ZZ-domain). The modified staphylococcal protein A (ZZ-domain) of the fusion protein is an immune response triggering region and CipA portion of the fusion protein is the cellulose binding region. Thus, the limitations of the claims are met. This is the same for the other art rejections under 35 U.S.C. §102.

Applicant needs to amend (change) the claims to clearly define what the fusion proteins contain and to distinguish the claimed fusion proteins from those in the cited references.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (Journal of Neuroscience, 2002, 22(12):4964-4972) or Chapin et al. (Journal of Cell Science, 1991, 98:27-36) or Shi et al. (Biotechnology Letters, 2003, 25(10):815-819) or Zhou et al. (Journal of Neuroscience Research, 2002, 67(5):625-633) or Kobatake et al. (Journal of Biotechnology, 1995, 35:263-268) or Lehtio et al.

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(PNAS, 2003, 100(2):484-489) and further in view of Whitlow et al. (U.S. Patent No. 5,856,456).

The claims are directed to fusion proteins comprising spacer or linker regions.

The cited reference do not teach spacer or linker regions. However, Whitlow et al. teaches the use of linkers and spacers between fusion partners to allow the resulting linked fusion polypeptide to properly fold into a conformation providing the desired biological activity and reduce steric hindrances.

Therefore, it would have been obvious for one of ordinary skill in the art to include spacers or linkers between fusion partners as suggested by Whitlow et al. to reduce steric hindrances and to allow the fusion partners to properly fold. There would have been a reasonable expectation of success as linkers and spacers are routinely used between fusion partners and given the successfully use of spacers and linkers by Whitlow et al.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White/  
Examiner, Art Unit 1648

/Stacy B Chen/  
Primary Examiner, Art Unit 1648